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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,324	10/13/2006	Bob Coyne	14923.0035	4626

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STEPTOE & JOHNSON LLP
1330 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER	
CHEN, CATHERYNE	
ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,324	COYNE ET AL.	
	Examiner	Art Unit	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,15-51,63 and 68-77* is/are pending in the application.

4a) Of the above claim(s) *37 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-10, 15-36, 39-51, 63, 68-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/28/08, 9/12/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Currently, Claims 1, 3-10, 15-51, 63, 68-77 are pending. Claims 1, 3-10, 15-51, 63, 68-77 are examined on the merits. Claims 2, 11-14, 52-58, 64-67 are canceled.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on Aug. 28, 2008 has been entered.

Election/Restrictions

Applicant's election without traverse of Group I (Claims 1-51, 59-64, 66-67, newly added 68-77), the species Lactococcus-derived bacteriocin, rosemary, phenolic diterpene being carnosic acid, phenolic triperpene being ursolic acid, raw meat, citric acid esters of monodiglycerides, polyphosphates in the reply filed on June 22, 2007 is acknowledged. Claims 37-38 are withdrawn.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-10, 15-36, 39-51, 63 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-10, 15-36, 39-40, 50-51, 63, 69-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bicchi et al. (2000, Phytochemical Analysis, 11, 236-242), Yang et al. (2001, Bioorganic & Medicinal Chemistry, 9, 347-356), Pol et al. (1999, Letters in Applied Microbiology, 29, 166-170), and Karatzas et al. (2000, J. Applied Microbiology, 89, 296-301).

Bicchi et al. teaches rosemary extracts of phenolic diterpenes, rosmarinic acid and caffeic acids, carnosic acid and carnosol (Introduction, paragraph 1). However, it does not teach nisin, carvacrol, carvone, and claimed concentrations.

Pol et al. teaches nisin is produced by Lactococcus lactis and is bactericidal against a broad range of Gram-positive bacteria (Introduction, paragraph 1). By combining nisin with plant essential oils, the restrictions in the use of nisin as a food preservative might be overcome and the range of applications could be expanded (Introduction, paragraph 2). Nisin is combined with carvacrol to determine bacteriostatic or bactericidal action of nisin and carvacrol (page 167, Results and Discussion, paragraph 2). Nisin and carvacrol concentrations of inhibition are temperature dependent (Table1). Concentration of nisin used is 5.3 microgram/mL and carvacrol is 0.7 mmol/L (Figure 1); 0.3 microgram/mL of nisin (Figure 2). Synergy between nisin and carvacrol enables use of lower amounts of both compounds for effective food preservation (page 169, right column, first sentence).

Karatzas et al. teaches carvone against Listeria monocytogenes (Abstract) at 5 mmol/L at 45 degree Celsius for 30 minutes (Discussion, paragraph 1). Carvacrol, thymol reduced viable numbers of L. monocytogenes grown at 8 degree Celsius at concentrations of 1.75 mmol/L, 1.5 mmol/L (page 300, paragraph 2). The design of effective combined processing is a complicated task that depends on a great number of factors such as micorbial target, the nature of the food, and consumer requirements and legislation (page 300, right column, paragraph 1).

Rosemary is considered to intrinsically teach the claimed phenolic diterpenes, triterpenes, ursolic acid and rosmarinic acid because both the reference and the claimed invention are using the same composition.

The references do not specifically teach combining antimicrobial agent, Labiatae family, nisin, carvacrol and carvone together. The references do teach that the compounds are bacteriocidal. Pol et al. teaches nisin is produced by Lactococcus lactis and is bactericidal against a broad range of Gram-positive bacteria (Introduction, paragraph 1). Bicchi et al. teaches rosemary extracts of phenolic diterpenes, rosmarinic acid and caffeic acids, carnosic acid and carnosol (Introduction, paragraph 1), where phenolic diterpenes are antimicorbials (see Yang et al., Abstract). Karatzas et al. teaches carvone against Listeria monocytogenes (Abstract). As discussed in MPEP 2144.06:

> It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.

Thus, is would be obvious to combine antimicrobial agent, Labiatae plant with nisin, carvacrol, carvone because they are taught in the reference to have the same purpose.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant for antimicrobials. The amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient) is clearly a result effective parameter that a

person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Claims 1, 3-10, 15-36, 39-41, 50-51, 63, 69-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bicchi et al. (2000, Phytochemical Analysis, 11, 236-242), Yang et al. (2001, Bioorganic & Medicinal Chemistry, 9, 347-356), Pol et al. (1999, Letters in Applied Microbiology, 29, 166-170), Karatzas et al. (2000, J. Applied Microbiology, 89, 296-301) as applied to claims 1, 3-10, 15-36, 39-40, 50-51, 63, 69-77 above, and further in view of Bard et al. (US 3679434).

Bicchi et al. teaches rosemary extracts of phenolic diterpenes, rosmarinic acid and caffeic acids, carnosic acid and carnosol (Introduction, paragraph 1). However, it does not teach nisin, carvacrol, carvone, raw meat, and claimed concentrations.

Pol et al. teaches nisin is produced by Lactococcus lactis and is bactericidal against a broad range of Gram-positive bacteria (Introduction, paragraph 1). By combining nisin with plant essential oils, the restrictions in the use of nisin as a food preservative might be overcome and the range of applications could be expanded (Introduction, paragraph 2). Nisin is combined with carvacrol to determine bacteriostatic or bactericidal action of nisin and carvacrol (page 167, Results and Discussion, paragraph 2). Nisin and carvacrol concentrations of inhibition are temperature dependent (Table1). Concentration of nisin used is 5.3 microgram/mL and carvacrol is 0.7 mmol/L (Figure 1); 0.3 microgram/mL of nisin (Figure 2). Synergy between nisin and carvacrol enables use of lower amounts of both compounds for effective food preservation (page 169, right column, first sentence).

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Bard et al. teaches fresh (uncured) meat with edible polyphosphate salts to prevent the development of rancidity (column 2, lines 65-69).

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Thus, is would be obvious to combine antimicrobial agent, Labiatae plant with nisin, carvacrol, carvone because they are taught in the reference to have the same purpose.

Meat can be spoiled by bacteria and undergoes oxidation. Thus, an artisan of ordinary skill would reasonably expect that anti-oxidants, antimicrobicidals, agents to prevent rancidity could be used as the types of composition taught by the references. This reasonable expectation of success

would motivate the artisan to use all of the claimed ingredients in the reference composition. Thus, using all of the claimed ingredient is considered an obvious modification of the references.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant for antimicrobials. The amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient) is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Claims 1, 3-10, 15-36, 39-43, 50-51, 63, 69-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bicchi et al. (2000, Phytochemical Analysis, 11, 236-242), Yang et al. (2001, Bioorganic & Medicinal Chemistry, 9, 347-356), Pol et al. (1999, Letters in Applied Microbiology, 29, 166-170), Karatzas et al. (2000, J. Applied Microbiology, 89, 296-301), Bard et al. (US

3679434) as applied to claims 1, 3-10, 15-36, 39-41, 50-51, 63, 69-77 above, and further in view of Todd, Jr. (US 5084293).

Bicchi et al. teaches rosemary extracts of phenolic diterpenes, rosmarinic acid and caffeic acids, carnosic acid and carnosol (Introduction, paragraph 1). However, it does not teach nisin, carvacrol, carvone, raw meat, emulsifier of citric acid esters of mono-diglycerides, and claimed concentrations.

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Todd, Jr. teaches antioxidant use for meats (column 1, lines 56-60), rosemary in food stuff (column 5, lines 55-58), emulsifier of citric acid esters of mono-diglycerides (column 18, line 18).

Rosemary is considered to intrinsically teach the claimed phenolic diterpenes, triterpenes, ursolic acid and rosmarinic acid because both the reference and the claimed invention are using the same composition.

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Bicchi et al. teaches rosemary extracts of phenolic diterpenes, rosmarinic acid and caffeic acids, carnosic acid and carnosol (Introduction, paragraph 1). However, it does not teach nisin, carvacrol, carvone, raw meat, emulsifier of citric acid esters of mono-diglycerides, lysozyme, polyphosphates, EDTA, and claimed concentrations.

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King et al. teaches antibacterial composition against gram positive bacteristatic of lytic enzymes, bacteriocins apply to solid food (Abstract), use of nisin as bactericides against bacterium Lactoccus lactis and against gram

negative bacteria (column 2, lines 43-59), lysozyme, polyphosphates, EDTA (column 3, lines 27-32).

Rosemary is considered to intrinsically teach the claimed phenolic diterpenes, triterpenes, ursolic acid and rosmarinic acid because both the reference and the claimed invention are using the same composition.

The references do not specifically teach combining antimicrobial agent, Labiatae family, nisin, carvacrol and carvone together. The references do teach that the compounds are bacteriocidal. Pol et al. teaches nisin is produced by Lactococcus lactis and is bactericidal against a broad range of Gram-positive bacteria (Introduction, paragraph 1). Bicchi et al. teaches rosemary extracts of phenolic diterpenes, rosmarinic acid and caffeic acids, carnosic acid and carnosol (Introduction, paragraph 1), where phenolic diterpenes are antimicorbials (see Yang et al., Abstract). Karatzas et al. teaches carvone against Listeria monocytogenes (Abstract). King et al. teaches antibacterial composition against gram positive bacteristatic of lytic enzymes, bacteriocins apply to solid food (Abstract). As discussed in MPEP 2144.06:

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Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michael V. Meller/
Primary Examiner, Art Unit 1655